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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,754	07/12/2006	Marc Karel Jozef Francois	PRD2166USPCT	1592

27777 7590 10/29/2010

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EXAMINER	
MILLIGAN, ADAM C	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
10/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/585,754	FRANCOIS ET AL.	
	Examiner	Art Unit	
	ADAM MILLIGAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-13* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1 and 3-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 3/8/2010, PROSECUTION IS HEREBY REOPENED. New grounds for rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below (see the end of the action).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 1 and 3-12 are under 35 U.S.C. 103(a) as being unpatentable over Heeres (WO 96/13499- See IDS dated 7/12/2006) in view of Basit et al. (The Effect of Polyethylene Glycol 400 on Gastrointestinal Transit: Implications for the Formation of

Poorly Water Soluble Drugs, Pharmaceutical Research, Volume 18, No. 8, 2001), the combination further in view of Chen (2002/0147201).

Heeres teaches a composition which may be in the form of a solution and is preferably for oral administration (p.10, lines 7-9). The composition may contain and active ingredient as well as glycols, sugars, and other common pharmaceutical media (i.e. additives) (p.10, lines 3-14). Mitratapide is disclosed to be an active ingredient (p.17, Compound 22). Oral additives include taste modifiers such as sodium saccharin. Heeres also teaches that when the composition is formulated for parenteral administration, other ingredients may be included to aid in solubility (p.10. lines 16-18). Heeres also teaches that acid addition salts of the compounds of formula (I) are obviously more suitable in the preparation of aqueous compositions due to their increased water solubility over the base form (p.10, lines 28-30).

Heeres does not teach the incorporation of an antioxidant or PEG 400 as a specific component of the composition which will increase the solubility of the mitratapide active agent.

Basit teaches that PEG 400 is a particularly preferred solubility enhancer for poorly water-soluble drugs because in addition to its superior ability to increase solubility of such drugs, PEG 400 concurrently reduces gastrointestinal transit time (Page 1149, Column 2). Therefore, PEG 400 is not only an inert pharmaceutical excipient (Page 1149, Column 2), but also has a positive effect on the bioavailability of the co-administered drug (Page 1149, Column 2).

Basit does not teach the inclusion of mitratapide.

Chen teaches the antioxidant butylated hydroxyanisole (BHA) is commonly included at 0-15% by weight to stabilize compositions (¶76). If the composition is for oral administration, it should have a preferable taste (¶7). Taste modifying agents are commonly employed for this purpose and may come in a variety of forms including sweeteners such as sucrose or sucralose at 0 to 10% by weight (Paragraph 61). Also, cyclodextrins may be included in the composition (¶75).

Chen does not teach the inclusion of mitratapide.

It would have been obvious to one of ordinary skill in the art to use solubility enhancing additives to the oral compositions of Heeres, given that Heeres teaches parenteral formulations can include ingredients to aide in solubility and that more soluble active ingredient salts are preferred. While the specific teaching for solubility enhancing additives is directed to parenteral formulations, the concept of increasing solubility in aqueous forms is relevant to all aqueous compositions, regardless their specifically stated administration form. In choosing additives to aid in solubility, the skilled artisan would have found it obvious to use the specific glycol of Basit, PEG 400, given that Heeres calls for the addition of glycols and Basit teach PEG 400 to be a known solubility enhancer which also provides additional benefits compared to other glycols.

Further, when choosing other common additives for oral administration, the skilled artisan would have found it obvious to incorporate the additives taught by Chen, given that Chen teaches these additives result in a composition having increased solubility and bioavailability of the active agent. Specifically, it would have been obvious

to complex the active agent with glycyrrhizin, as taught by Chen to increase the solubility of the active ingredient.

Further yet, it would have been obvious to incorporate other taste modifying agents, such as sucralose, as taught by Chen, given that the Heeres teaches the incorporation of taste modifying agents. See MPEP 2143(A).

Note, while the pharmaceutically acceptable solvent is defined in instant claim 1 as a selected from the Markush group, the claim is modified by the transition phrase "comprising", therefore the composition may have an additional pharmaceutically acceptable solvent, such as water, in combination with the specifically recited pharmaceutically acceptable solvent.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

/ADAM MILLIGAN/
Examiner, Art Unit 1612